



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,591	06/13/2000	Gary K. Michelson	101.0078-00000	5619
22882	7590	02/06/2004	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/06/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/593,591

Applicant(s)

MICHELSON, GARY K.

Examiner

Paul B. Prebilio

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-129 and 148-282 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-129 and 148-282 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3738

Upon review of the response filed November 14, 2003, the Examiner noticed that the number of claims was more than doubled to a new total of 264 claims. This number of claims is considered an excessive burden and clouds prosecution of the case by presenting too many issues for consideration. Applicant is respectfully requested to consider substantially reducing the number of claims for any future prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, there is no enabling disclosure of how to make a combination of a bone ring also including bone composite material. Rather, only "cortical bone, plastics, and composite plastics" are described in the specification; see page 11, lines 11-12 of the original specification. There is no description of using a bone composite with the bone, and how any of these materials would be oriented with respect to each other. For this reason, one would not know how to make and/or use the claimed invention because there is no teaching of how to do so.

Claims 242 and 282 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

Art Unit: 3738

that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The open-ended range of at least 2 screw holes is considered to constitute new matter with respect to the original specification, which discloses up to 4 screw holes. Furthermore, the specification does not adequately enable an implant with many more than 4 holes such that the claimed range is not enabled for the entire range.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 175, 195, 215, 235, 255, and 275 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim scope of these claims is considered to be indefinite because it depends upon the size of the implantee's vertebrae; see MPEP 2173.05(b), fourth paragraph which is inserted herein by reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 3738

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-22, 25, 30-35, 43-63, 71-77, 85-106, 109, 114-119, 127-129, 148, 153, 158, 163, 171, 174, 175, 179, 180, 183, 184, 188-191, 193-195, 199, 200, 203, 204, 208-211, 213-215, 219, 220, 223, 224, 228-231, 233-235, 239, 240, 243, 244, 248-251, 253-355, 259, 260, 263, 264, 268-271, 273-275, 279, and 280 are rejected under 35 U.S.C. 102(e) as anticipated by Boyle et al (US 6,277,149) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyle et al (US 6,277,149) alone.

Boyle discloses a bone ring obtained from a long bone (Figures 5, 10, 12, and column 2, lines 28-55). The modifier "generally" for straight is considered a broad term that is reads on the disclosure of Figures 10 and 12 of Boyle, which is slightly curved. Alternatively, the new "generally straight" limitation reads on the ridges (24) and grooves (28) or equivalent of Boyle, which elements run alongside the perimeter of the trailing edge.

Alternatively, if one does not consider the Section 102 interpretation as untenable because the straight leading edge is not circumferentially oriented in Boyle, this interpretation would lead one to conclude that Boyle lacks the generally straight leading edge section as claimed. However, at the time the invention was made, it would have

Art Unit: 3738

been an obvious matter of design choice to a person of ordinary skill in the art to flatten a side of the Boyle implant because Applicants have not disclosed that a flattened leading edge provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well. Furthermore, Boyle has some embodiments where there are flat circumferential surface. Therefore, it would have been an obvious matter of design choice to modify Boyle to obtain the invention as specified in the claims.

Regarding claims 25 and 109, the plural openings are the pores in the bone that are naturally present in such material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-29, 67-70, 110-113, 149-152, 155-157, 159-162, 172, 177, 178, 182, 197, 198, 202, 212, 217, 218, 222, 232, 237, 238, 242, 252, 257, 258, 262, 272, 277, 278, and 282 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Kozak et al (US 5,397,364). Boyle meets the claim language as explained above but lacks the screw holes and screws as claimed. However, Kozak teaches that it was known to put multiple bone screws in similar implants as a means to secure them; see Figures 24 and 25 and the textual description

Art Unit: 3738

of these figures. Therefore, it is the Examiner's position that it would have been obvious to use bone screws and have holes for them in the Boyle implant for the same reasons that Kozak uses the same: to secure the implant to the adjacent bone.

With regard to claims 28 and 29, it is the Examiner's position that it would have been prima facie obvious to make the bone screws and other bone implant components out of bone because the ring itself is made of that material. Since the ring itself is made of bone material, it would have been obvious to make the other parts of the implant out of the same material because it would have all the advantages and purposes that led Boyle to make the bone ring out of bone or composites of bone.

With regard to claim 155, it is the Examiner's position that it would have been prima facie obvious to have more than two bone screw openings since both one and two bone screws and their openings are taught by Boyle.

Claims 36-42, 78-84, 120-126, 165-170, 181, 185-187, 201, 205-207, 221, 225-227, 241, 245-247, 261, 265-267, and 281 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) alone. Boyle et al meets the claim language except for the types of growth promoting substances claimed. However, the Examiner posits that the type of growth promoting substance would have been prima facie obvious over Boyle et al alone because there is no criticality for such types shown or demonstrated. For example, in column 4, lines 10-13, Boyle discloses putting bone growth material into the opening (26). The specific type of bone implant material claimed would amount to a substitution of a functionally equivalent bone growth material for another one as disclosed by Boyle. For this reason, it would have been prima facie

Art Unit: 3738

obvious to an ordinary artisan to substitute one bone growth material for another since the other one would function equally well.

With regard to claim 72, Boyle et al does not disclose the use of a bioresorbable plastic as claimed. However, the Examiner gave Official notice that bioresorbable plastics are known and used in the art. Applicant failed to traverse this assertion so the Examiner asserts that he acquiesced to the Examiner's assertion. Hence, it is the Examiner's position that it would have been obvious to do the same in the Boyle et al invention for the same reasons that the prior art uses the same. With regard to claim 165, Boyle teaches straight sides in other embodiments; see Figures 1, 4, 7, 13, 14, 17, and 21. Therefore, it is the Examiner's position that it would have been prima facie obvious to use straight sides on the embodiment of Figure 10 because Applicants have not disclosed that a straight side provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because even Boyles other embodiments have straight sides. Therefore, it would have been an obvious matter of design choice to modify Boyle to obtain the invention as specified in the claims.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Gross et al (US 5,306,308). Boyle et al does not disclose the use of a bioresorbable plastic as claimed. However, Gross et al (US 5,306,308) teaches that it was known to coat similar implants with the bioresorbable plastic polylactide in order to encourage bone ingrowth. Therefore, it would have been obvious

Art Unit: 3738

to coat the Boyle et al implant with polylactide in order to promote bone ingrowth as taught by Gross et al.

Claims 23, 24, 64, 65, 107, 108, 176, 196, 216, 236, 256, and 276 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Zdeblick et al (US 5,669,909). Boyle et al meets or renders obvious the claim language but fails to disclose more than one bore through the upper and lower surfaces as claimed. Zdeblick et al, however, teaches that it was known to have more than one hole in similar implants; see the figures. Hence, it is the Examiner's position that it would have been obvious to have two or more holes in the Boyle et al implant for the same reasons that Zdeblick et al has the same and in order to promote greater ingrowth.

Response to Arguments

Applicant's arguments filed November 14, 2003 have been fully considered but they are not persuasive.

In response to the traversal of the claim 31 Section 112, first paragraph rejection, the Examiner is of the position that the cited sections do not provide enablement for a combination of whole bone with a bone composite portion as the present claims requires. For this reason, the rejection has been maintained.

In response to the traversal that Boyle does not teach generally straight leading edges, the Examiner has modified the rejection to explain that "generally" is a broad term that can be read on by Boyle.

Art Unit: 3738

In response to the traversal that were reasons given for the straight leading edges, the Examiner reviewed the sections cited and found that these sections do not specifically address the straight edges or side issue and are too general in nature. For this reason, Applicant's argument that the design of the implant having straight leading edges is not considered persuasive because the specification does not support this assertion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilit
Primary Examiner
Art Unit 3738